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10/770,138	02/02/2004	Paul John Rennie	9510	9660

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EXAMINER	
CARTER, KENDRA D	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/770,138	RENNIE ET AL.	
	Examiner	Art Unit	
	Kendra D. Carter	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8-10 and 12-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 8-10, and 12-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges the applicant's remarks and arguments of June 6, 2007 made to the office action filed January 4, 2007. Claims 1-5, 8-10, and 12-15 are pending. Claims 1, 8-10 and 12 are amended and claims 6, 7, and 11 are cancelled.

In light of the amendments, the 35 USC 112, first paragraph rejection is withdrawn.

The Applicant's arguments of the 35 U.S.C. 103(a) rejection of claims 1-5 and 11-15 as being unpatentable over Gelber et al. (US 2001/0044410 A1) in view of Adams et al. (US 2004/0077601) were not found persuasive, and thus upheld.

The Applicant's arguments of the 35 U.S.C. 103(a) rejection of claims 6-8 and 10 as being unpatentable over Gelber et al. in view of Adams et al. as applied to claims 1-5 and 11-15 above and in further view of Kamishita et al. (US 5,158,761) were not found persuasive, and thus upheld.

The Applicant's arguments of the 35 U.S.C. 103(a) rejection of claims 6-8 and 10 as being unpatentable over Gelber et al. in view of Adams et al., in further view of Kamishita et al. as applied to claims 1-8 and 10-15 above and in further view of Betbeder et al. (US 6,017,513) were not found persuasive, and thus upheld.

The Applicant's arguments are addressed below.

Due to the amendment to the claims, the new 35 U.S.C. 103(a) rejections are made below.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. The treatment of SARS is not disclosed in the prior-filed application 09/692,634 or 09/421,131 and therefore has an effective filling date of 02/02/2004. The respiratory tract composition is not disclosed in the prior-filed application 09/421,131, but is disclosed in the 09/692,634 application, thus the effective filling date for the composition is 10/19/2000.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(1) Claims 1-5, 8-10 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gelber et al. (US 2001/0044410 A1) in view of Adams et al. (US 2004/0077601), in view of Kamishita et al. (5,158,761), and in further view of Beerse et al. (US 6,294,186 B1).

Gelber et al. teaches a method and composition that treats a condition caused by an immune response to a virus (see abstract, lines 1, 5-6, and 13-15) and respiratory system (see page 5, paragraph 56, lines 2-3). The aqueous saline solution of the composition can be applied by a spray, which is administered onto the nasal mucosa (see page 7, paragraph 69, lines 8-10; addresses applicant's claims 11-15). Preferred ingredients for the formulation include zinc acetate, zinc gluconate, zinc oxide, citric acid (see page 5, table 3; addresses applicant's claims 1 in part and 3-5), and ascorbic acid (see page 2, paragraph 13, column 2, line 1 and page 3, paragraph 31, line 15; addresses applicant's claim 1 in part). In regards to the pH of the composition, it is inherent that the composition have a pH from about 3.0 to about 5.5 because Gelber et al. teaches a composition comprising ascorbic acid, which has a pH of about 3. Zinc gluconate is administered in the range of approximately 0.1 mg to 15mg (see page 9, paragraph 73, line 30; addresses applicant's claim 1 in part) or 2.5 mg to 30 mg (see page 10, paragraph 85, lines 8-9). Ascorbic acid is administered in the range of approximately 50 mg to 1000 mg (see page 9, paragraph 73, line 33; addresses applicant's claim 1 in part).

Gelber et al. does not specifically teach a method of treating SARS. Gelber et al. also does not teach a composition comprising a mucoadhesive polymer (applicant's claim 1c and 8), specifically poloxamers and ethylhydroxy ethylcelluloses (applicant's claim 9); a viscosity of from about 1 cps to about 2000 cps (applicant's claim 1d); a sensate (applicant's claim 1d); or a pH adjusting agent (applicant's claim 10).

Adams et al. teaches a method of stimulating an immune response of a viral infection (see claim 134) such as a SARS infection (see claim 137; addresses applicant's claim 1 in part). The administration of the method may be delivered in the form of an aerosol spray (see page 40, paragraph 361, line 3) mucosally (see page 40, paragraph 364, line 2) to the nose (see page 41, line 8).

Kamishita et al. teaches a spray base gel composition comprising an aqueous solution of carboxyvinyl polymer with a water-soluble basic substance with a viscosity within the range of 500-5,000 cps (see abstract; lines 1, and 3-6; addresses applicant's claims 1d and 12-14). A pH value of the spray gel is adjusted to the desired pH with a water-soluble basic substance such as sodium hydroxide (see column 3, lines 40 and 42) or other pH adjustors taking into consideration the stability or absorption of an active medicament (see column 4, lines 25-29; addresses applicant's claim 10). In order to improve the spread-stick property in sprays of an aqueous solution and increase the viscosity, generally thickeners such as hydroxypropyl cellulose, hydroxypropyl

methylcellulose and polyvinylpyrrolidone (PVP) are used (see column 1, lines 59-66, column 7, table 1, lines 3, 4, and 6; addresses applicant's claims 1c and 8). The pH of the composition rages from 4-9 (see claim 1, line 3; addresses applicant's claim 1). The preparation is applied to mucous membranes in the nasal cavity (see column 6, lines 47-50; addresses applicant's claims 11-13 and 15). The preparation is useful in a clinical use, like an influenza vaccine (see column 6, lines 11-13).

Beerse et al. teaches antimicrobial compositions comprising an effective amount of a benzoic acid analog, a metal salts such as Mn, Ag, Zn, Sn, Fe, Cu, Al, Ni, Co, Ti and combinations thereof (see column 7, lines 2, 8 and 9) and a dermatologically acceptable carrier wherein the composition has a pH of from about 1 to about 7 which provide enhanced immediate as well as residual anti-viral efficacy against viruses (see abstract, lines 1-3, 7, and 10-12; addresses claim 1). The method is used to treat the area of the nose, nasal canal or passage (see column 47, lines 34-36 and examples 39 and 40). The carrier of the present invention may comprise an aqueous solution with about 0.01% to about 10% of one or more thickeners such as polymeric materials such as methyl cellulose, carboxymethyl cellulose, hydroxyl propylmethyl cellulose (see column 9, lines 55 and 60-63; column 10, lines 39 and 40; and column 26, line 56), hydroxyethyl ethylcellulose (i.e. ethylhydroxy ethylcellulose; see column 37, line 2; addresses claims 1c, 8 and 9). As a preferred embodiment, where the composition is to be in contact with human keratinous tissue (i.e. nose) a wide variety of non-limiting cosmetic and pharmaceutical ingredients commonly used in the personal car industry

are suitable for use in the compositions of the invention (see column 19, lines 57, 58 and 65-67), such as skin sensates (see column 20, line 4). Skin sensates can be present at a level of from about 0.01% to about 10% or it can be modified to provide the desired level of consumer perceived sensation (see column 43, lines 65-67 to column 44, lines 1-5; addresses claim 1d).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Gelber et al. with a method to treat SARS is because of the following teachings: (1) Adams et al. teaches a method of treating a viral infection, particularly SARS with a nasal spray composition and (2) Gelber et al. teaches compositions to treat viral infections that are respiratory infections. The motivation to combine a method of Gelber et al. with a method to treat SARS is because Gelber et al. teaches compositions to treat viral infections, particularly respiratory infections (i.e. influenza). Thus, since SARS is a respiratory infection caused by a virus, and Gleber et al. (see abstract, lines 5-6 and see page 5, paragraph 56, lines 2-3) compositions and methods treat viral infections, particularly respiratory infections, then the compositions of Gleber et al. would treat SARS.

To one of ordinary skill in the art it would be obvious to combine the composition of Gleber et al. with a viscosity of from about 1 cps to about 2000 cps, and a pH adjusting agent is because (1) both Kamishita et al. and Gleber et al. teach aqueous, nasal spray respiratory anti-viral compositions and methods that are applied to the nasal

mucosal tissue; and (2) Kamishita et al. teaches a composition having a pH of 4-7 (see claim 1, line 3) with a viscosity of 500-5,000 cps (see claim 1, line 3), comprising hydroxypropyl cellulose or hydroxymethyl cellulose (see column 1, lines 59-66, column 7, table 1, lines 3, 4, and 6), and the pH adjuster sodium hydroxide see column 3, lines 40 and 42).

The motivation to combine a composition of Gelber et al. and Adams et al. with a mucoadhesive polymer, a pH adjustor, and a viscosity of from about 1 cps to about 2000 cps is because Kamishita et al. teaches a composition comprising a pH adjustor (i.e sodium hydroxide; see column 3, lines 40 and 42) and wherein the composition has a viscosity within the range of 500-5000 cp so that (1) the particle size distribution of the spray after spraying is 80% in the area of 20-100 μm (see column 3, lines 10-16), (2) the spead-stick property of the spray may be effective (see column 1, lines 59-62), and (3) to keep in consideration the stability or absorption of an active medicament (see column 4, lines 25-29). Thus, having a composition comprising a pH adjustor and a viscosity of from about 1 cps to about 2000 cps would increase the efficacy of the spray to treat SARS by providing excellent spray base properties (see column 2, lines 40-45). A prima facie case of obviousness typically exists when the ranges of a claimed composition overlap the ranges disclosed in the prior art. E.g., In re Geusler, 116 F.3d 1465, 1469, 43 USPQ2d 1362, 1365 (Fed. Cir. 1997); In re Woodruff, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936-37 (CCPA 1976); In re Malagari, 449 F.2d 1297, 1202, 182 USPQ 549, 553 (CCPA 1974). It is the normal desire of scientists or artisans to

improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980) ("[D]iscovery of an optimum value of the result effective variable in a known process is ordinarily within the skill of the art." See, e.g., In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *In re Paterson* Appeal No. 02-1189 (Fed. Cir. January 8, 2003).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Gelber et al. and a sensate is because the following teachings: (1) both Gelber et al. and Beerse et al. teach a metal salt composition that treat antiviral conditions that an be applied nasally; (2) Beerse et al. teaches a wide variety of non-limiting cosmetic and pharmaceutical ingredients commonly used in the personal care industry are suitable for use in the compositions of the invention (see column 19, lines 57, 58 and 65-67), such as skin sensates (see column 20, line 4); and (3) Beerse et al. continues to teach that the skin sensates can be present at a level of from about 0.01% to about 10% or it can be modified to provide the desired level of consumer perceived sensation (see column 43, lines 65-67 to column 44, lines 1-5). Thus, the motivation to include the sensate is because sensates are commonly used in personal care for the patient's (i.e. consumer) perceived sensation and it is used in anti-viral compositions as taught by Beerse et al.

To one of ordinary skill in the art it would be obvious to combine the composition of Gleber et al. and a mucoadhesive polymer selected from polymeric cellulose derivatives selected from those disclosed in claim 8 and thermoreversible polymers selected from poloxamers or ethylhydroxy ethylcelluloses and mixtures thereof from about 0.01% to about 20% because of the following teachings: (1) Kamishita et al., Beerse et al. and Gleber et al. all teach aqueous, nasal anti-viral compositions and methods; (2) Kamishita et al. teaches a composition comprising hydroxypropyl cellulose or hydroxymethyl cellulose (see column 1, lines 59-66, column 7, table 1, lines 3, 4, and 6); (3) Beerse et al. teaches a composition comprising from about 0.01% to about 10% thickeners such as polymeric materials such as methyl cellulose, carboxymethyl cellulose, hydroxyl propylmethyl cellulose (see column 9, lines 55 and 60-63; column 10, lines 39 and 40), hydroxyethyl ethylcellulose (i.e. ethylhydroxy ethylcellulose; see column 37, line 2); and (4) although hydroxyethyl ethyl cellulose is not labeled as a thermoreversible polymer, products of identical chemical composition can not have mutually exclusive properties *In re Spada*, 911 F. 2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Thus, the use of mucoadhesive polymers and specifically thermoreversible polymers selected from claims 8 and 9 are known in the art to be used in nasal anti-viral compositions to treat viral conditions as taught by Kamishia et al. and Beerse et al.

(2) Claim 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gelber et al. (US 2001/0044410 A1) in view of Adams et al. (US 2004/0077601), in view of Kamishita et al. (US 5,158,761), and in further view of Beerse et al. (US 6,294,186 B1), as applied to claims 1-5, 8-10 and 12-15 above, and in further view of Betbeder et al. (6,017,513).

Gelber et al. in view of Adams et al., and in further view of Kamishita et al., in further view of Beerse et al. teachings are as applied to claims 1-5, 8-10 and 12-15 above.

Gelber et al., Adams et al., Kamishita et al., and Beerse et al. do not teach a composition comprising the mucoadhesive polymer as a thermoreversible polymer being poloxamers from about 0.01% to about 20% by weight.

Betbeder et al. teaches the use of an amphiphilic compound such as poloaxamers, modified polyoxyethylene and other surface active compounds (see column 7, lines 22-23) for the use in a nasal (see column 4, line 45) mucosal administration (see abstract line 1) to reduce the effect of a virus infection (see column 8, lines 33-34, 38 and 47-48).

To one of ordinary skill in the art at the time of the invention, it would be obvious to combine the method and compositions of Gelber et al., Adams et. al., Kamishita et

al., and Beerse et al. with the mucoadhesive polymers selected from the group consisting of poloxamers from about 0.01% to about 20% by weight is because (1) Betbeder et al. teaches the use of an amphiphilic compound such as poloaxamers, modified polyoxyethylene and other surface active compounds (see column 7, lines 22-23) for the use in a nasal (see column 4, line 45) mucosal administration (see abstract line 1) to reduce the effect of a virus infection (see column 8, lines 33-34, 38 and 47-48); (2) Kamishita et al. teaches the use of the mucoadhesive polymers hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyvinylpyrrolidone (PVP) (see column 1, lines 59-66, column 7, table 1, lines 3, 4, and 6), and carboxyvinyl polymers (see abstract; line 1) in a nasal mucosal composition to treat viral infections (see column 6, lines 47-50); (3) Beerse et al. teaches an anti-viral composition comprising about 0.01% to about 10% of one or more thickeners such as polymeric materials such as methyl cellulose, carboxymethyl cellulose, hydroxyl propylmethyl cellulose (see column 9, lines 55 and 60-63; column 10, lines 39 and 40; and column 26, line 56), hydroxyethyl ethylcellulose (i.e. ethylhydroxy ethylcellulose; thermoreversible polymers; see column 37, line 2); (4) poloxamers, ethylhydroxy ethylcelluloses, PVP, carboxyvinyl polymers, PVP and hydroxypropyl methylcellulose are all mucoadhesive polymers; (5) mucoadhesive polymers are known within the art to be used in nasal compositions; and (6) "Products of identical chemical composition can not have mutually exclusive properties." Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F. 2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The motivation to combine the method and compositions of Gelber et al , Adams et. al., Kamishita et al., and Beerse et al. with the mucoadhesive polymers selected from the group consisting of poloxamers, ethylhydroxy ethylcelluloses and mixtures thereof is because mucoadhesive polymers are known within the art to be used in nasal compositions as shown by Kamishita et al. Additionally, Betbeder et al. demonstrates that the specific poloaxamer is used to confer a physico-chemical environment appropriate to the substance, the mode of mucosal administration, and the desired effect (see column 7, lines 1-3). Thus, one skilled in the art would be able to choose the appropriate mucoadhesive polymer for the composition, since they are commonly used in nasal compositions.

Response to Arguments

Applicant's arguments filed June 6, 2007 have been fully considered but they are not persuasive.

The Applicant addressed the arguments towards the amended claims and not the claims that were originally examined. Thus, the Examiner's response to the arguments are limited to those pertaining to the claims that were originally examined

because a new 35 USC 103(a) rejection has been made to address the amendments to the claims.

Claims 1-5 and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gelber et al. (US 2001/0044410 A1) in view of Adams et al. (US 2004/0077601).

> The applicant argues that Gerber fails to teach or suggest a method of treating SARS by administering a nasal respiratory tract composition disclosed in the amended claim 1. Particularly, the amounts of zinc gluconate and ascorbic acid are disclosed in an example that describes a composition administered in liquid form not a nasal composition.

The examiner disagrees because of the reasons given above in the office action. In terms of the amounts of zinc gluconate and ascorbic acid being disclosed in a liquid form but not a nasal composition, the example demonstrates that the amounts of these components in a liquid composition to meet the limitation of claim 1a (i.e. from about 0.001% to about 20% by weight of an organic acid, claim 1b (i.e. from about 0.01% to about 20% by weight of a metal compound, and claim 12 (i.e. nasal liquid). As for the composition being nasal, this limitation is also disclosed by Gerber because the aqueous saline solution of the composition can be applied by a spray, which is administered onto the nasal mucosa (see page 7, paragraph 69, lines 8-10).

> The applicant argues that Adams does not teach or suggest a method of treating SARS by administering a nasal respiratory tract composition disclosed in the amended claim 1. Particularly, Adams teaches that administration by inhalation is for treating lung tumors (see paragraph 361) and the administration of antibodies and antigens mucosally (see

> paragraph 364). On page 41, line 8, the description is for the route of infection of antigens i.e. mucosal surfaces such as oral, nasal, vaginal, penile and rectal and has nothing to do with a method of treating SARS by administering a nasal respiratory tract composition having a pH of from about 3.0 to about 5.5 to areas of the upper respiratory tract. Thus, alone or the combination of Gerber and Adams do not teach or suggest all the claim limitations of the amended claim 1 and do not establish a prima facie case of obviousness.

The examiner disagrees because of the reasons given above in the office action. In terms of the administration by inhalation to treat lung tumors, this is just one example of the invention, but the method as a whole can be administered to stimulate an immune response of a viral infection (see claim 134) such as a SARS infection (see claim 137; addresses applicant's claim 1 in part). The administration of the method may be delivered in the form of an aerosol spray (see page 40, paragraph 361, line 3) mucosally (see page 40, paragraph 364, line 2) to the nose (see page 41, line 8). The respiratory tract composition of the originally examined claim 1 is taught by Gelber. The amended respiratory tract composition of claims 1 is taught by Gelber et al. in view of Adams et al., in view of Kamishita et al. and in further view of Beerse et al. as discussed in the above office action.

Claims 6-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gelber et al. (US 2001/0044410 A1), in view of Adams et al. (US 2004/0077601) as applied to claims 1-5 and 11-15 above and in further view of Kamishita et al. (5,158,761).

The applicant asserts that the arguments presented above regarding Gerber et al. in view of Adams et al. apply to the present rejection. Kamishita et al. fails to teach or suggest about 0.01% to about 30% by weight of a mucoadhesive polymer selected from polymeric cellulose derivatives and thermoreversible polymers where the composition has a viscosity of from about 1 cps to about 2000 cps and where the cellulose derivative is selected from the group consisting of hydroxypropyl methylcellulsoes, hydroxypropyl celluloses, methyl cellulose polymers, carboxymethyl cellulose polymers, salts of carboxymethyl cellulose. Additionally, Kamishita does not cure the lack of disclosure to a method of treating SARS by administering a nasal respiratory tract composition disclosed in the amended claim 1.

The Examiner's response for Gerber et al. and Adams et al. arguments above apply to this argument. The examiner agrees that the amounts of the mucoadhesive polymer and thermoreversible polymers are not taught by Kamishita, but these limitations were amended into claims 1, which all new limitation are addressed in the new 35 USC 103(a) rejection above. Kamishita teaches the mucoadhesive polymers hydroxypropyl cellulose, hydroxypropyl methylcellulose and polyvinylpyrrolidone (PVP) as thickeners (see column 1, lines 59-66, column 7, table 1, lines 3, 4, and 6) and a water-soluble basic substance with a viscosity within the range of 500-5,000 cps (see abstract; lines 1, and 3-6). "Products of identical chemical composition can not have mutually exclusive properties." Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F. 2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claim 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gelber et al. (US 2001/0044410 A1) in view of Adams et al. (US 2004/0077601), in further view of Kamishita et al. (5,158,761), as applied to claims 1-8 and 10-15 above and in further view of Betbeder et al. (6,017,513).

> The applicant asserts that the arguments presented above regarding Gerber et al. in view of Adams et al. in view of Kamishita et al. apply to the present rejection. Betbeber et al. fails to teach or suggest a composition comprising from about 0.01% to about 30% by weight of a mucoadhesive polymer selected from polymeric cellulose derivatives and thermoreversible polymers wherein the mucoadhesive polymer is a thermoreversible polymer selected from the group consisting of poloxamers, ethylhydroxy ethylcelluloses, and mixtures thereof.

The examiner disagrees. The Examiner's response for Gerber et al. and Adams et al. arguments above apply to this argument. The above limitations were amended into claims 1, which all new limitation are addressed in the new 35 USC 103(a) rejection above. Betbeder et al. teaches the use of an amphiphilic compound such as poloaxamers, modified polyoxyethylene and other surface active compounds (see column 7, lines 22-23) for the use in a nasal (see column 4, line 45) mucosal administration (see abstract line 1) to reduce the effect of a virus infection (see column 8, lines 33-34, 38 and 47-48). The amounts are obvious from the teachings of Beerse et al. above.

To one of ordinary skill in the art at the time of the invention, it would be obvious to combine the method and compositions of Gelber et al., Adams et. al., Kamishita et

al., and Beerse et al. with the mucoadhesive polymers selected from the group consisting of poloxamers from about 0.01% to about 20% by weight is because (1) Betbeder et al. teaches the use of an amphiphilic compound such as poloaxamers, modified polyoxyethylene and other surface active compounds (see column 7, lines 22-23) for the use in a nasal (see column 4, line 45) mucosal administration (see abstract line 1) to reduce the effect of a virus infection (see column 8, lines 33-34, 38 and 47-48); (2) Kamishita et al. teaches the use of the mucoadhesive polymers hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyvinylpyrrolidone (PVP) (see column 1, lines 59-66, column 7, table 1, lines 3, 4, and 6), and carboxyvinyl polymers (see abstract; line 1) in a nasal mucosal composition to treat viral infections (see column 6, lines 47-50); (3) Beerse et al. teaches an anti-viral composition comprising about 0.01% to about 10% of one or more thickeners such as polymeric materials such as methyl cellulose, carboxymethyl cellulose, hydroxyl propylmethyl cellulose (see column 9, lines 55 and 60-63; column 10, lines 39 and 40; and column 26, line 56), hydroxyethyl ethylcellulose (i.e. ethylhydroxy ethylcellulose; thermoreversible polymers; see column 37, line 2); (4) poloxamers, ethylhydroxy ethylcelluloses, PVP, carboxyvinyl polymers, PVP and hydroxypropyl methylcellulose are all mucoadhesive polymers; (5) mucoadhesive polymers are known within the art to be used in nasal compositions; and (6) "Products of identical chemical composition can not have mutually exclusive properties." Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F. 2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The motivation to combine the method and compositions of Gelber et al , Adams et. al., Kamishita et al., and Beerse et al. with the mucoadhesive polymers selected from the group consisting of poloxamers, ethylhydroxy ethylcelluloses and mixtures thereof is because mucoadhesive polymers are known within the art to be used in nasal compositions as shown by Kamishita et al. Additionally, Betbeder et al. demonstrates that the specific poloaxamer is used to confer a physico-chemical environment appropriate to the substance, the mode of mucosal administration, and the desired effect (see column 7, lines 1-3). Thus, one skilled in the art would be able to choose the appropriate mucoadhesive polymer for the composition, since they are commonly used in nasal compositions.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kendra D. Carter whose telephone number is (571) 272-9034. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KDC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER